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Subject: NEWS UPDATES: EPA's New NCEA Chief Sees NAAQS As Model For Chemical Assessments

EPA's New NCEA Chief Sees NAAQS As Model For Chemical Assessments
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Kenneth Olden, the new director of EPA's National Center for Environmental Assessment (NCEA), says the scientific review process for the agency's national ambient air quality standards (NAAQS) could serve as a model for his plan to overhaul the controversial Integrated Risk Information System (IRIS) assessments NCEA produces, including adopting the NAAQS' review process's focus on stakeholder input early in the review process.

In a Sept. 27 interview with *Inside EPA*, Olden also outlined other goals including new ways to consider susceptibility, cumulative exposures and other factors in IRIS studies, and launching new research efforts combining genetics, environment, diet, behavior and chemical exposure to create cumulative assessments.

Olden, whom EPA named to the slot last May, served as director of the National Institute of Environmental Health Sciences (NIEHS) and its National Toxicology Program (NTP) between 1991 and 2005. After he left NIEHS, he served as the founding dean of the School of Public Health at Hunter College, City University of New York.

The NCEA slot has been filled in an acting capacity by Rebecca Clark, the center's permanent deputy, when EPA's former research chief Paul Anastas moved former NCEA director Peter Preuss to a new role as chief innovation officer for ORD in 2010.

Olden said that as NCEA director he is reviewing NCEA's four main responsibilities: IRIS assessments of chemicals' toxicities; integrated science assessments (ISA) providing key data on criteria air pollutants' risks to inform NAAQS reviews; provisionally peer-reviewed toxicological values -- preliminary risk assessments used at site cleanups for chemicals without an IRIS assessment -- and its research programs in human health and ecological risk assessment and global change.

"I think we do three of our responsibilities very well," said Olden, who took on the position of NCEA director in July. "The area where we have a problem is IRIS, and that has gotten most of my attention."

A National Research Council (NRC) committee is reviewing the IRIS program to address alleged flaws in the process for and methods of assessing chemicals' risks, a key concern for the chemical industry as EPA often uses the IRIS studies to underpin many of its rulemakings. At the first meeting of the NRC review panel Sept. 17, Olden vowed to adopt an aggressive set of initiatives aimed at making the program more transparent and addressing a host of industry concerns (*Risk Policy Report*, Sept. 24).

To further bolster IRIS assessments, Olden said he plans to use the ISA process as a model for IRIS -- a suggestion first raised in the NRC's 2011 review criticizing EPA's draft formaldehyde risk assessment. The report included an extra chapter beyond the committee's charge that broadly addressed a number of concerns about the IRIS program. The report encouraged the agency to look to the example of the ISA program, which over the course of two years was revamped into what the committee considered a model program. ISAs are comprehensive reviews of policy-relevant science on the six criteria pollutants regulated under NAAQS, including ozone and particulate matter. EPA staff craft the ISAs early in the Clean Air Act-mandated five-year review cycle for the NAAQS. The ISAs include conclusions on the science of the pollutants' health effects, and inform risk and exposure assessments in which staff develop quantitative characterizations of exposures and risks.

Those studies then form the basis for a policy assessment in which staff outline a recommended level to set a NAAQS, based on an air law mandate to set a standard requisite to protect public health.

EPA's Clean Air Scientific Advisory Committee (CASAC) reviews all of the documents, and public comment is accepted at each stage in the process -- including public testimony during CASAC's meetings.

"People who know the history of ISA know that it hasn't always been that way. It is what it is because of John Vandenberg's leadership," Olden said of the director of NCEA's Research Triangle Park division, which does most of the ISA work. "He's coming here to be my senior advisor [on IRIS]. I think there are some best practices with ISA that we can learn from."

Olden pointed to Vandenberg's efforts to reach out for more stakeholder input in ISAs as a key model for the IRIS program. Olden added that already, NCEA is beginning to implement this model, noting it held a Sept. 27 meeting for internal stakeholders -- EPA program office staff -- to discuss the long-stalled IRIS assessment of inorganic arsenic, which NCEA recently restarted in preparation for a new NRC review (*Risk Policy Report*, July 23).

"This is the first time we've done that," Olden said, describing the internal stakeholder meeting as "an effort to define the problem with inorganic arsenic, scope the problem and discuss data gaps."

Such meetings will be "a step for each assessment going forward. In the end, it will save us time. Important [IRIS] reports are often held up [near finalization] by a big disagreement or new studies," he said.

Olden noted that the arsenic meeting, part of which he attended, included "vigorous discussion and debate about what we need." Such meetings have been held in the past by Vandenberg's group for ISAs. The meetings are a "best practice" from ISA that he intends to adopt for IRIS, Olden said.

Olden also praised EPA's IRIS staff, saying that, "we have an excellent team of people. I have confidence in them." The most important factor, Olden said, is that staff at NCEA are "open and accessible. We want to be transparent. We will listen, though that doesn't mean we'll take every suggestion, we will listen."

Olden reiterated promises from his remarks at NRC that each IRIS assessment will begin with a public meeting to discuss the chemical at issue, data available to characterize its potential hazard and data gaps that could be filled with new research funded by EPA or industry, as well as crafting a standard procedure for literature searches. Olden's remarks were met with appreciation from industry representatives who spoke at the NRC meeting.

Olden indicated that he is meeting with Linda Birnbaum, director of NIEHS to discuss that agency's computer algorithm for initiating literature searches, an approach Olden indicated he has interest in pursuing for IRIS. Olden said that NIEHS, like NCEA, is "focusing on systematic reviews, they're trying to achieve the same thing that I'm trying to achieve: a transparent, standardized process, so we can't be accused of . . . cherry-picking the data . . . more importantly, using computer algorithms, we can also identify data gaps. Then we'll know what endpoints we'll be looking at. We can agree on these things."

Olden compared the changes he is making to the IRIS program to its previous process, started during Preuss' leadership. "Now, we

spend two to three years in a cave by ourselves and then release a draft [IRIS assessment]," Olden said. He added that in that time, new research could be undertaken. "We can put in place rules, studies have to be done [by a date certain] to be considered [in the assessment]. We just need to communicate. People are reasonable. I think we can make IRIS a shining example."

Olden also pointed to longer-term changes he wants to make to IRIS, including efforts to incorporate new -omics data, and ways of considering susceptibility, cumulative exposures and non-chemical stressors in assessments. "I'm most interested in social and behavioral [information], which we don't include because we don't have databases," Olden said. "I'd like to see us [create] such a database so we can begin to understand" the effects of these issues on risk. He noted that EPA advisors have urged the agency to address social and behavioral factors. "That's where risk assessment is going," Olden said. "We have to do risk assessment in the context of the real world where people live."

Olden also hopes to launch a major research effort related to epigenetics -- combining genetics, environment, diet, behavior and chemical exposure to create cumulative assessments. "It's well known that the environment induces changes in DNA and the chromatid. That will probably turn out to be very important in terms of environmental risk assessment and the development of human diseases," Olden said. "There's no doubt about it. The next big wave of research . . . is to look at how the environment, social, behavioral and economic factors impact one's risk for exposure to environmental chemicals. It's the next frontier, I predict."

"So I'm interested in developing that kind of a study here at the agency, and we're having discussions about it," Olden said. "NIEHS is funding some work there. What I'm gonna propose is a bigger project. And that some government agency has to step up and take the lead, and I'd like to see that be the [EPA]. No one is looking at it from a public health prospective. It is an environmental issue. And we are an environmental agency, we are a public health agency."

Olden suggested the agency could launch such a project relatively cheaply and easily in animals, using lab rats and mice with the same genetics and exposing them to different environments.

Calling such a project a "landmark study," he compared it to the magnitude of the National Institutes of Health's multimillion-dollar, decade-long Human Genome Project. -- *Maria Hegstad*

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